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8 **UNITED STATES DISTRICT COURT**  
9 **SOUTHERN DISTRICT OF CALIFORNIA**

10 THE REGENTS OF THE  
11 UNIVERSITY OF CALIFORNIA,  
12  
13 vs. Plaintiff,  
14 PAUL S. AISEN, et al.,  
15 Defendants.

CASE NO. 15-cv-1766-BEN (BLM)

**ORDER GRANTING  
DEFENDANTS' MOTION FOR  
CLARIFICATION OR  
MODIFICATION OF THE  
PRELIMINARY INJUNCTION**

16  
17 **I. INTRODUCTION**

18 Now before the Court is Defendants' Motion to Clarify or Modify the  
19 Preliminary Injunction Issued by the State Court. Defendants allege that changed  
20 circumstances necessitate modification, or at least, clarification of the preliminary  
21 injunction order. Plaintiff disagrees. The evidence suggests that circumstances  
22 have changed significantly since the time the preliminary injunction order was  
23 entered. Moreover, the Special Master has asked for clarification. At least  
24 clarification, and perhaps modification is necessary. Therefore, the motion is  
25 granted.

26 **II. APPLICABLE LAW**

27 The Supreme Court teaches that when questions arise as to the interpretation  
28 or application of an injunction order, a party should seek clarification or

1 modification from the issuing court, rather than risk disobedience and contempt.  
 2 *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 192 (1949) (“Yet if there were  
 3 extenuating circumstances or if the decree was too burdensome in operation, there  
 4 was a method of relief. . . . Respondents could have petitioned the District Court for  
 5 a modification, clarification or construction of the order.”); *Regal Knitwear Co. v.*  
 6 *NLRB*, 324 U.S. 9, 15 (1945) (“If defendants enter upon transactions which raise  
 7 doubts as to the applicability of the injunction, they may petition the court granting  
 8 it for a modification or construction of the order.”). Defendants filed this motion for  
 9 clarification or modification shortly after circumstances changed and not long after  
 10 questions were raised by the Special Master. Because “courts no less than parties  
 11 desire to avoid unwitting contempts,” *Regal*, 324 U.S. at 15, clarification or  
 12 modification is warranted.

### 13 **III. THE PRELIMINARY INJUNCTION ORDER**

14 The difficulty with this type of case stems from the medical delicacy and  
 15 technological complexity of the Alzheimer’s Disease Cooperative Study (“ADCS”)  
 16 Data and Systems which are the subject of the preliminary injunction order. The  
 17 preliminary injunction was crafted in such a way as to safeguard from destruction a  
 18 significant public resource: longitudinal medical research and its informational  
 19 databases about treatments for Alzheimer’s Disease. Because the informational  
 20 databases include computer data files, they must be managed by experts in digital  
 21 technology. Because the studies are ongoing, disruptions in data access or loss of  
 22 data may have serious adverse impacts on patients today.

23 On August 4, 2015, a preliminary injunction was issued on the basis that  
 24 Plaintiff “has demonstrated ownership and a right to control and manage certain  
 25 data and systems, the control and management of which have been taken over by  
 26 Defendants.” (Preliminary Injunction at 1-2.) The ADCS Systems and Data were  
 27 ordered transferred to the “possession, custody, and control of UCSD and its duly  
 28

1 authorized employees, *consistent with the terms of the contracts and grants to*  
2 *which UCSD is a party.*” (*Id.* at 2 (emphasis added).) The Special Master is “to  
3 ensure that the process is completed in a comprehensive, technically appropriate,  
4 and timely manner, and without prejudicing UCSD, or causing any avoidable risk of  
5 harm to the rights or interests of third parties.” (*Id.* at 3-4.)

6 The preliminary injunction order anticipates change. It anticipates that a  
7 study sponsor (the term “third party” is used in the text) may assign its rights to  
8 obtain access, custody, or control over the ADCS data, and it may assign its rights  
9 to the Defendants. At the time the preliminary injunction issued, Plaintiff was  
10 responsible for managing all of the ADCS studies.

11 Not long after, however, five of the six major study sponsors transferred their  
12 studies to Defendant University of Southern California. The five major studies are  
13 the FYN study with Yale, the INI study with Wake Forest, the two ADNI Studies,  
14 and the A4 Study with Lilly. In addition to the five major studies, another study,  
15 LEARN, which is an offshoot of the major A4 Study, has also transferred to  
16 Defendant University of Southern California. Defs.’ Mot. to Clarify or Modify,  
17 Aisen Decl. ¶ 37, Exs. J, K, & L; Barton Decl. ¶ 6; Sperling, M.D., Decl. ¶ 4. As a  
18 result, by maintaining custody and control over some ADCS Systems and Data,  
19 Defendants may be acting in compliance with the preliminary injunction by virtue  
20 of acting in the shoes of the transferred Study Sponsors, while at the same time be  
21 violating the order to the extent they are acting on their own behalf. Not only does  
22 this make difficult the task of enforcing the ordered return of systems and data to  
23 the Plaintiff, it will require a re-transfer of systems and data back to the Defendants  
24 for the transferred studies. Medical research is complicated enough. Large scale  
25 data management is complicated enough.

26 Defendants filed their motion for clarification or modification only two weeks  
27 after questions were raised by the Special Master. *See* Notice of Lodging of Special  
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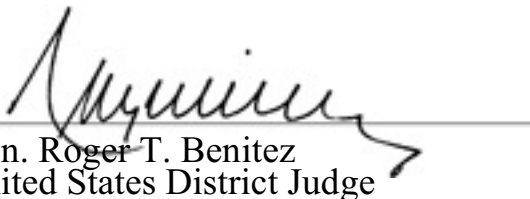
1 Master's Interim Report (9/2/15), Dkt. #14. The Special Master wrote, "[o]n  
2 September 2, 2015 the 'Interim Report of the Special Master and Consultant' was  
3 lodged with this Court by Defendants on the Special Master's behalf . . . . The  
4 Interim Report updated the Court on the status of the Special Master's work, and  
5 *requested three clarifications* of the Preliminary Injunction." See Notice of  
6 Lodging of Directive of the Special Master (9/11/15), at 6, Dkt. #20 (emphasis  
7 added). The Defendants need clarification and the Special Master needs  
8 clarification.

#### 9 IV. CONCLUSION

10 Therefore, the motion is granted. The preliminary injunction order will be  
11 clarified or modified if still warranted by the current state of events. However, time  
12 has passed since the briefing on the motion. Consequently, the parties are directed  
13 to file new briefs.

14 Defendants shall file by October 3, 2016, a new brief setting forth their  
15 requested clarifications or modifications. Plaintiff may file a response by October  
16 24, 2016. It is requested that the Special Master file a statement setting forth his  
17 own requested clarifications or modifications by October 17, 2016. Either party  
18 may file a response to the Special Master's statement by October 31, 2016. A  
19 hearing will be set by the Court thereafter.

20  
21 DATED: August 30, 2016

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Hon. Roger T. Benitez  
United States District Judge